UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: All Cases	

TENNESSEE CLINIC DEFENDANTS'
RESPONSE TO FDA'S MOTION FOR PROTECTIVE ORDER

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, A Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively "Tennessee Clinic Defendants") oppose the U.S. Food and Drug Administration's Motion for a Protective Order[1] that seeks to quash the subpoena for Fed. R. Civ. P. 30(b)(6) deposition testimony of the U.S. Food and Drug Administration (hereinafter "FDA") and implement an indefinite stay of discovery of the FDA. The Court should deny the FDA's Motion for Protective Order and instead compel deposition testimony and document production[2] by the FDA.

[1] Dkt. 1838.
[2] The FDA asks for the Court to take the extraordinary step of shielding it from a deposition until the not-yet-set-for-trial criminal case against the NECC Insiders resolves. The FDA has agreed, at least in principle, to begin production of documents, but no actual production has occurred.

INTRODUCTION

The FDA's motion perfectly illustrates the fundamental tension in these cases. On one hand, the PSC advocates for a rush of multiple cases to trial within this calendar year.[3] However, on the other hand, the Tennessee Clinic Defendants are unable to conduct discovery of the essential players in the litigation.

NECC, the owners and operators of NECC, and, here, the FDA, simply refuse to fully participate in discovery.[4]

Specifically, NECC refuses to produce a corporate representative, claiming that the defendants should be satisfied with a "dump" of thousands of self-selected documents.[5] The multiple Insider Defendants all refuse to answer written discovery or appear for depositions, hiding behind a blanket Fifth Amendment invocation.[6] The NECC-related entities, which also hold important information, likewise refuse to answer written discovery and produce witnesses for depositions.[7] Now, with the instant motion, the FDA refuses to produce a witness for a deposition, citing the U.S. Attorneys' ongoing criminal prosecution of NECC's owners and employees.

This tension – if the PSC and the parties resisting discovery have their way – will lead to rushed trials with incomplete discovery and extreme prejudice to the Tennessee Clinic Defendants.

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[3] *See* PSC's Motion to Set, Dkt. 1716.

[4] Ironically, the undeniably at-fault wrongdoers, NECC and its Insiders, seek to take advantage of the fact that NECC voluntarily bankrupted and that they have been indicted for criminal offenses as shields to participating in discovery. It is also ironic that the governmental body that failed to shut down NECC despite concerning reports about its practices seeks to use the prosecution of NECC by another governmental body to shield the FDA from participating in discovery. The only entities fully participating in discovery are the health care providers who unknowingly received tainted medications despite assurances of safety, and two relatively tangential players, Liberty and UniFirst.

[5] Dkt. 1810, 1811.

[6] Dkt. 1823.

[7] *See, e.g.*, Dkt. 1854.

If these cases are to be fairly tried, the Defendants *must* be given access to the information and witnesses necessary to develop their defenses. Requiring the Tennessee Clinic Defendants to defend these cases without essential information and testimony (like the information and testimony the FDA holds) is patently unfair and overwhelmingly prejudicial.[8]

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With this backdrop, the FDA now refuses to produce a witness for a 30(b)(6) deposition. It asks the Court make an exception for the FDA that allows it to avoid giving testimony while the criminal prosecution of NECC's owners and employees is pending. Of note, the FDA's objection appears to center *only* on the timing of the 30(b)(6) deposition.[9] The FDA does not dispute that it holds information relevant to the Tennessee Clinic Defendants' defenses in this case, for obvious reasons. (Indeed, the FDA acknowledges that the United States Attorney's Office "has provided the criminal defendants with approximately 8.7 million pages of discovery."[10]) Likewise, the FDA does not argue the Tennessee Clinic Defendants are not entitled to take its 30(b)(6) deposition. (This point is incontrovertible. The Federal Rules of Civil Procedure expressly permit deposing a government agency like the FDA.)

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[8] The Tennessee Clinic Defendants' need for meaningful discovery is even more compelling given that they are not on even footing with the PSC. The PSC gained possession of thousands of documents from several Defendants through mediation and settlement negotiations. The PSC has, in many instances, refused to produce clearly discoverable documents obtained from other defendants in the mediation process. *See* Tennessee Clinic Defendants' *Omnibus Motion to Compel the PSC to Respond to Discovery Served by the Tennessee Clinic Defendants and Motion to Deem Requests Admitted* (Dkt. 1830).

[9] Dkt. 1838-1, p. 6.

[10] *See* Dkt. 1838-3, p. 4.

Instead, despite holding relevant documents and testimony, the FDA insists that because fourteen (14) individuals – all owners or employees of NECC – have been indicted for their conduct in operating NECC, *the FDA* should not be required to comply with the Tennessee Clinic Defendants' subpoena for deposition testimony until after the criminal proceedings conclude.

The FDA has not met its burden to demonstrate the need for a stay of its 30(b)(6) deposition.[11] Even if the Court finds that the FDA has good reason for a stay of its 30(b)(6) deposition, the overwhelming prejudice to the Tennessee Clinic Defendants that would result if the FDA is exempted from giving testimony far outweighs any burden on the FDA.

[11] Although the FDA asks for a stay only of its deposition, such a stay would effectively stay the entire litigation. A primary piece of the Tennessee Clinic Defendants' defense of these cases is its assertion of comparative fault against the FDA. A related important piece of the Tennessee Clinic Defendants' defense of these cases is to establish that the FDA (1) did nothing to dissuade purchasers of medications from buying from compounding pharmacies and (2) tacitly approved by its inaction NECC as a safe supplier of medications. Finally, the FDA will likely have factual information regarding NECC's operation that cannot be obtained from the Insiders due to the Fifth Amendment privilege. Quite simply, without discovery – specifically, testimony – from the FDA, the Tennessee Clinic Defendants are denied information to support essential planks of their defense.

LAW AND ARGUMENT

I. The Tennessee Clinic Defendants Cannot Defend These Cases Without the Testimony of FDA Witnesses.

As explained at length below, the FDA has failed miserably to meet the high burden to justify a stay. At the outset, to contextualize this dispute, it must be recognized that FDA testimony is essential to the Tennessee Clinic Defendants' defense of the lawsuits against them.

First, the FDA has discoverable information that will help the Tennessee Clinic Defendants rebut the Plaintiffs' claims against them.

For instance, the Plaintiffs claim that, had the Tennessee Clinic Defendants just queried the FDA for information about NECC before buying from them, they would have learned of NECC's problems and bought from a different manufacturer. Deposition testimony is necessary to show that the FDA would have provided *no* information about NECC other than a single warning letter from 2006.

The Tennessee Clinic Defendants also contend that the FDA issued no formal warnings to providers against using compounded drugs or, specifically, products from NECC.[12] If the Tennessee Clinic Defendants can establish that the FDA did not issue warnings to health care providers about the dangers of compounded medications before 2012, it would bolster the Tennessee Clinic Defendants' position that purchasing from compounding pharmacies was appropriate. This requires a deposition of the FDA.

These are just two examples where the FDA's testimony is key to central case issues.

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[12] However, the Plaintiffs contend that the FDA warned health care providers before 2012 of the dangers of compounded medications. [*Reed* Complaint, ¶ 249(e) (alleging negligence for "fail[ing] to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company")].

Second, the Tennessee Clinic Defendants assert comparative fault against the FDA for breaching its duty to the clinics that purchased from NECC and the patients who received NECC's products from their health care providers.[13] Based on the non-public information the FDA had prior to the outbreak, it should have shut down NECC, or at the very least, adequately warned NECC's customers.[14] The Tennessee Clinic Defendants need the FDA testimony to establish and support their comparative fault defense.[15]

Third, the FDA's deposition testimony will help develop the Tennessee Clinic Defendants' comparative fault claims against other parties and non-parties, including NECC. For instance, the FDA found various problems with NECC's sterility processes both before and after the discovery of the outbreak. Presumably, at least some of the millions of documents the Government disclosed to the criminal defendants are relevant to the Tennessee Clinic Defendants' comparative fault claim that NECC acted negligently and caused the contamination and injuries. FDA testimony is thus also necessary to establish the fault of NECC.[16]

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[13] *Carroll v. Whitney*, 29 S.W.3d 14, 19 (Tenn. 2000) (holding that jury may apportion fault to immune nonparties).

[14] For instance, from 2008-12, the FDA received multiple complaints about NECC that it did not make public and did not act upon. The Tennessee Clinic Defendants' detailed comparative fault allegations against the FDA are at Answer of STOPNC, *et al.*, Dkt. 1455, p. 79-90.

[15] Importantly, much of this relevant evidence would have no bearing on the criminal cases if disclosed to the Tennessee Clinic Defendants. For example, testimony about the FDA's knowledge of NECC prior to the outbreak, its enforcement actions against NECC, and its coordinated efforts with the Massachusetts Board of Registration in Pharmacy all revolve around the *FDA's* conduct. This evidence would support comparative fault claims against the FDA and the Massachusetts Board of Registration in Pharmacy without divulging information about the Government's criminal prosecution.

[16] Likewise, on a more basic level, FDA testimony is necessary to establish the authenticity of the FDA's documents and to address other basic evidentiary issues so that the documents may be admitted at trial.

The FDA does not deny it possesses evidence *relevant* to the Tennessee Clinic Defendants' defenses and assertions of comparative fault. However, that concession does not adequately explain the *importance* of the FDA's evidence to the defense of these cases. The evidence – particularly, testimony – is an indispensable component of the Tennessee Clinic Defendants' defenses. Without it, the jury gets an incomplete picture and the Defendants an incomplete defense.

II. The FDA Has Not Met the High Burden Required to Justify a Stay of Discovery due to Pending Criminal Proceedings.

Without even parsing the factors necessary for the Court to issue a stay (which are discussed in the next section), it is obvious that the FDA has not met its high burden to justify a stay of discovery.

As this Court knows, parallel civil and criminal proceedings are common and not objectionable as long as the parties' rights are not substantially prejudiced.[17] Federal courts often permit simultaneous civil and criminal actions against the same defendants involving the same transactions.[18] The Supreme Court expressly approved parallel civil and criminal actions, even where a government agency is a party to the civil action.[19]

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[17] *Securities and Exch. Comm'n v. Dresser Indus., Inc.*, 628 F.2d 1368, 1375 (D.C. Cir. 1980) (*en banc*).
[18] *SEC v. First Fin. Grp.*, 659 F.2d 660, 665 (5th Cir. 1981).
[19] *United States v. Kordel*, 397 U.S. 1 (1970) ("It would stultify enforcement of federal law to require a governmental agency such as the FDA invariably to choose either to forgo recommendation of a criminal prosecution once it seeks civil relief, or to defer civil proceedings pending the ultimate outcome of a criminal trial.").

A stay of a civil case until the conclusion of a related criminal prosecution is "an extraordinary remedy."[20] The party seeking a stay "bears the burden of establishing its need,"[21] and the movant must demonstrate a "clear case of hardship" to be granted a discretionary stay.[22]

Reflecting the high burden required to stay parallel civil litigation, courts in numerous cases have refused to stay civil proceedings despite parallel criminal cases.[23] Two cases are illustrative.

In *Driver v. Helms*, the district court rejected some of the same arguments for a stay that the FDA puts forth here.[24] In *Driver*, the district court found that the fact that some defendants in a civil case related to an alleged program of opening first-class mail were also subject to a criminal investigation did not require the court to stay the civil proceedings, even though it was argued that some defendants might assert their Fifth Amendment privileges and that civil discovery might be used to obtain details of the Government's criminal case.[25]

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[20] *Trs. of Plumbers & Pipefitters Nat'l Pension Fund v. Transworld Mech., Inc.*, 886 F. Supp. 1134, 1139 (S.D.N.Y. 1995).
[21] *Clinton v. Jones*, 520 U.S. 681, 708 (1997).
[22] *Austin v. Unarco Indus., Inc.*, 705 F.2d 1, 5 (1st Cir. 1983); *GLL GmbH & Co. Messeturm KG v. LaVecchia*, 247 F.R.D. 231, 233 (D. Me. 2008) (denying stay where movant failed to demonstrate overriding hardship); *In re Scrap Metal Antitrust Litig.*, No. 1:02-CV-0844, 2002 WL 31988168, at *2 (N.D. Ohio Nov. 7, 2002) ("[Movant] for a stay must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay for which he prays will work damage to someone else.").
[23] *See, e.g., Int'l. Floor Crafts, Inc. v. Adams*, 529 F. Supp. 2d 174, 176 (D. Mass. 2007); *Digital Equipment Corp. v. Currier Enter.*, 142 F.R.D. 8 (D. Mass. 1991); *Horn v. District of Columbia*, 210 F.R.D. 13, 16 (D. D.C. 2002) (denying government motion to stay parallel civil action brought by target of federal criminal investigation because the government failed to make an adequate showing of hardship).
[24] 402 F. Supp. 683, 685 (D. R.I. 1975).
[25] *Id.* at 685.

In *Securities Exchange Commission v. Kornman*, the district court rejected similar arguments.[26] The defendant was charged in a criminal action for the same conduct that formed the basis of a civil complaint filed by the SEC.[27] In the civil action, the defendant served subpoenas on and planned depositions of several third parties.[28]

In response, the government filed an application for a stay of the civil proceedings, arguing that "it would likely be prejudiced if the criminal defendant, who is also the defendant in this civil suit, were furnished an opportunity to use the civil discovery process to, for instance, take depositions to obtain information learned through the government's criminal investigation or to obtain information that would not otherwise be available to him through the criminal discovery process."[29]

The magistrate judge in *Kornman* denied the government's motion, holding, "the Government had not met its burden of establishing 'substantial and irreparable prejudice' if a stay [was] not entered."[30]

Here, the FDA's argument that the Insider Defendants may obtain some details about the prosecution's criminal case through the FDA's deposition mirrors the Government's objections that were rejected in *Driver* and *Kornman*. Because the FDA has failed to meet the high burden required to stay civil proceedings due to a parallel criminal action, the FDA's Motion for Protective Order must be denied.

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[26] No. 3:04 Civ. 1803, 2006 WL 1506954, *1-4 (N.D. Tex. May 31, 2006).
[27] *Id.* at *1-4.
[28] *Id.* at *1-4.
[29] *Id.*
[30] *Id.* at *2.

Perhaps more importantly, application of the factors set forth for considering whether to impose a stay further exposes the FDA's failure to carry its burden.

III. The FDA's Motion for Protective Order Fails the First Circuit's Seven-Factor Test.

The First Circuit applies a seven-factor test for courts to consider when determining whether to stay civil proceedings while a concurrent criminal case proceeds:

1) The interests of the civil plaintiff in proceeding expeditiously with the civil litigation

2) The hardship to the defendant, including the burden placed upon him should the cases go forward in tandem

3) The convenience of both the civil and criminal courts

4) The interests of third parties

5) The public interest

6) The good faith of the litigants (or the absence of it)

7) The status of the cases.[31]

When applied to the present case, these factors overwhelmingly weigh against the FDA's Motion for Protective Order.[32]

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[31] *Microfinancial, Inc. v. Premier Holidays Int'l*, 385 F.3d 72, 78 (1st Cir. 2004); *S.E.C. v. TelexFree, Inc.*, 52 F. Supp. 3d 349, 352 (D. Mass. 2014).

[32] The factors are presented frequently in the case law in the context of the *defendant* asking for a stay of the proceedings because of a pending criminal case against the *defendant*. Here, a third-party is asking for the stay. The factors, thus, must be applied in a slightly different way.

A. The Plaintiffs' Interests Weigh against a Stay of the Civil Proceedings.

The first factor, the Plaintiffs' interest in proceeding with the civil litigation, weighs against a stay, albeit not as strongly as the PSC would have the Court believe. The Plaintiffs are interested in pushing these cases to trial as soon as possible. The Tennessee Clinic Defendants, frankly, agree that these cases should proceed to trial as soon as *reasonably* possible, but do not support the Plaintiffs' view that they should proceed to trial whether or not the Tennessee Clinic Defendants are able to do the discovery they need to defend the cases.

The Plaintiffs have reached a settlement of $200 million with the primary wrongdoers in these cases. Payment from that fund, presumably, will be made expeditiously. Thus, while the Plaintiffs still seek more money from the remaining defendants, they will soon receive payment from the substantial pot of money from NECC, the Affiliated, and National Defendants. This lessens the need to rush these cases to trial.

The Plaintiffs may argue that the FDA deposition must proceed to avoid a stay, crying out that "justice delayed is justice denied." But, make no mistake; it would be hugely beneficial to the Plaintiffs to rush these cases to trial without the opportunity for the Tennessee Clinic Defendants to depose the FDA.[33]

[33] The same principle applies with respect to NECC and the Insider Defendants. The PSC may pay lip service to the notion that discovery of the FDA, NECC, and the Affiliated Defendants must proceed, but the PSC's actions in refusing to level the playing field in terms of the information and documents that have been produced reveals the PSC's real goal – force the Tennessee Clinic Defendants to defend the cases against them without a fair opportunity to obtain the discovery necessary to support their defenses.

While the Plaintiffs' interest in moving these cases toward trial weighs against a stay, that interest must be considered in the context of (1) the large settlement the Plaintiffs have already reached and (2) the incentive to the Plaintiffs to rush the cases to trial without allowing the Tennessee Clinic Defendants to develop essential defenses.

B. The Lack of Hardship on the FDA Weighs against a Stay.

The second factor looks at the hardship on the party asking for the stay if the civil and criminal cases proceed in tandem and, here, weighs against imposing a stay.

First, most of the information that the Tennessee Clinic Defendants wish to develop in a deposition of the FDA deals with the actions *of the FDA*, not the criminal fault of NECC's owners and operators. Thus, the FDA should have no concern that development of such testimony will undermine the criminal prosecution of the Insiders.

Second, testimony developed about the wrongful conduct of NECC in contaminating the medications will only *help* the criminal prosecution of NECC's Insiders. The Tennessee Clinic Defendants share the Government's interest in proving the fault of NECC and its owners and employees because any fault proven against the true wrongdoers reduces any fault that can be attributed to the Tennessee Clinic Defendants. The Tennessee Clinic Defendants certainly do not seek to *help* the NECC owners' and employees' defense of the criminal case.

Third, the burden of preparing an FDA witness for a 30(b)(6) deposition is minimal relative to the size of the civil and criminal litigation. Preparation of one witness (or a few witnesses, if necessary to cover the topics) is a small endeavor in a criminal litigation that covers almost ten million documents and is termed "one of the highest priorities of the USAO" and "one of the most significant federal prosecutions currently ongoing in the United States."[34]

Simply put, the FDA has failed to demonstrate hardship sufficient to justify a stay.

C. The Convenience to the Courts Weighs against a Stay.

This Court has an interest in resolving this MDL both efficiently and fairly. The purpose of multidistrict litigation is to address common issues in cases pending in different districts, to avoid duplication of discovery, and to conserve the resources of the parties, their counsel and the judiciary. It would frustrate the MDL's purpose to postpone the litigation indefinitely, simply because the FDA claims that providing discovery to the Tennessee Clinic Defendants would hamper the Government's criminal case against the Insider Defendants.

In *Gordon v. Federal Deposit Ins. Corp.*, the court explained,

> "[T]he fact that a man is indicted cannot give him a blank check to block all civil litigation on the same or related underlying subject matter. Justice is meted out in both civil and criminal litigation. The overall interest of the courts that justice be done may very well require that the compensation and remedy due a civil plaintiff should not be delayed . . . ."[35]

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[34] Dkt. 1838-3.

[35] 427 F.2d 578, 580 (D.C. Cir. 1970); *see also General Dynamics Corp. v. Selb Mfg. Co.*, 481 F.2d 1204, 1213 (8th Cir. 1973).

Likewise, the FDA does not have a "blank check" to block this civil litigation simply because it plans to try criminal cases against the Insider Defendants. The Government offers scant support for its claims that its deposition testimony would hinder the criminal case against the Insider Defendants. The FDA offers only conclusory claims that its testimony would "prematurely and broadly disclose essential elements of the Government's case-in-chief, allowing the criminal defendants to tailor defenses to fit the anticipated proof."[36] [37] If the Court wishes to push these civil cases to trial in a timely manner, the FDA must be deposed, and the Court should not simply accept the FDA's broad, conclusory statements about the impact of an FDA deposition on the criminal prosecution.

D. Third-Party Interests Are Not Relevant to Consideration of a Stay.

The FDA does not allege that its deposition testimony would impair any third parties other than the USAO's prosecution of the Insiders.

E. The Public Interest Does Not Justify the Imposition of a Stay.

The FDA argues, without support, that the public will benefit from delaying the civil cases until the resolution of the criminal cases. However, federal courts have held that the public's interest in resolving civil matters may outweigh the interest in prosecuting the defendants in parallel criminal cases.

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[36] Dkt. 1838-1, p. 17.

[37] Similarly, the FDA argues that deposition testimony *might* reveal information about the agency's investigatory actions, could *potentially* lead to identification of non-FDA witnesses, and *might* prompt additional discovery requests in this litigation. The remote potential for additional discovery requests does not justify a stay. Furthermore, the FDA does not explain how its production of nearly *nine million* documents did not already convey information it says may be revealed to the criminal defendants through a deposition in the civil litigation.

In *United States v. Simon*, the Second Circuit reversed the district court's order staying civil discovery for 90 days because the public's interest in resolving the trustee's suit outweighed the defendants' interest in preventing pre-trial discovery of their factual contentions in a parallel criminal proceeding.[38]

Likewise, in *S.E.C. v. K2 Unlimited, Inc.*, the District Court for the District of Massachusetts denied a stay of discovery because the case had already been pending for three (3) years, and a stay would have been against the public interest and jeopardized evidence through fading memories and possible deaths of witnesses.[39]

Here, the public interest requires denying the stay and proceeding with civil discovery. It is undisputed that the meningitis outbreak was a public health crisis. Following its investigation into the FDA's role in the meningitis outbreak, Congress explained:

> "One of FDA's fundamental reasons for existence is to protect the public health by assuring the safety of our nation's drug supply. With respect to NECC and Ameridose, documents produced to the Committee raise serious questions about whether FDA repeatedly failed in its core mission. . . .The agency's inaction in the face of years of complaints and red flags associated with the safety of both companies' products and underlying practices had a tragic ending. While nobody could have fully anticipated the scope of this terrible outbreak, FDA was on notice that something like this might occur."[40]

The FDA cannot divert attention away from its role in causing the meningitis outbreak, nor shield itself from civil discovery, behind a shallow claim that prosecutors would be impaired in their ability to prosecute the Insider Defendants.

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[38] *United States v. Simon*, 373 F.2d 649 (2nd Cir. 1967), *judgment vacated on other grounds*, 389 U.S. 425 (1967).
[39] *S.E.C. v. K2 Unlimited, Inc.*, 15 F. Supp. 3d 158, 160 (D. Mass. 2014).
[40] FDA'S OVERSIGHT OF NECC AND AMERIDOSE: A HISTORY OF MISSED OPPORTUNITIES, p. 39 *available at* http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf (last accessed 5/22/15).

Furthermore, the citizens most affected by the meningitis outbreak are the hundreds of Plaintiffs and the clinics that purchased from NECC. Proceeding with this litigation, following discovery, would *serve* the public interest.

The Government's claim that the FDA's deposition testimony "could generate substantial pretrial publicity" that "could affect the ability to seat a fair and impartial jury" is not credible. The FDA admits "the USAO's criminal investigation has generated substantial coverage in both national and local media for more than two years."[41] The Insider Defendants are named as defendants by over 600 Plaintiffs from numerous states. Glenn Chin was arrested at the airport allegedly attempting to flee to Hong Kong.[42] The Insider Defendants were again the subject of national attention when they were arrested, with mugshots and video of the arrests appearing across numerous news outlets.[43]

The FDA has failed to show that, given the widespread publicity and attention this case has already received, its deposition testimony, which can be designated confidential under the Court's Third Amended Protective order,[44] would further affect the Court's ability to seat a fair and impartial jury in the criminal trial.

While impairment to the Government's criminal case against the criminal defendants is the most valid reason for supporting a stay of the proceedings, the FDA failed to demonstrate a "clear case of hardship" and that it would be substantially prejudiced if compelled to testify.[45]

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[41] Dkt. 1838-1, p. 19.
[42] http://www.bostonglobe.com/metro/2014/fedsmake-arrest-logan-compounding-pharmacy-case-rajklmPf9WVZxS73XYBw2H/story.html.
[43] http://boston.cbslocal.com/2013/12/17/necc-owner-employees-arrested-in-deadly-meningitis-outbreak/.
[44] Dkt. 814.
[45] *See Clinton*, 520 U.S. at 708; *Austin*, 705 F.2d at 5.

F. There Are No Improper Motives of the Litigants to Justify a Stay.

Stays of civil discovery are likely where a criminal defendant seeks to use the civil rules to obtain disclosure of the Government's evidence or vice versa.[46] Here, the party seeking discovery is not the criminal defendant. There has been no showing – or even an allegation – of bad faith in seeking deposition testimony from the FDA. The Tennessee Clinic Defendants – not the criminal defendants – seek to depose the FDA to obtain information necessary to defend the civil cases against them. Accordingly, this factor weighs against imposition of a stay.

G. The Status of the Cases Weighs against a Stay.

The current status of the civil and criminal cases weighs against the imposition of a stay. The FDA waited two years to indict NECC's owners and employees, and now asks this Court to delay the civil case (that has been proceeding efficiently for roughly two years) until the trial of the criminal case is complete, or plea agreements are struck. However, currently, *there is no trial date in the criminal case*, and the Government provides no timeframe for when it expects the criminal case to resolve. In essence, the FDA seeks to delay the entire civil case indefinitely. The FDA's testimony will affect comparative fault claims by clinics across the country, and a stay will stop this MDL in its tracks. This would unduly burden all of the parties in the MDL.[47]

[46] *See, e.g., Campbell v. Eastland*, 307 F.2d 478 (5th Cir. 1962), *cert. denied*, 317 U.S. 955 (1963); *Perry v. McGuire*, 36 F.R.D. 272 (S.D.N.Y. 1964).
[47] *See Sterling Nat. Bank v. A-1 Hotels Int'l, Inc.*, 175 F. Supp. 2d 573, 580 (S.D.N.Y. 2001).

"The case for staying civil proceedings is 'a far weaker one' when '[n]o indictment has been returned [and] no Fifth Amendment privilege is threatened.'"[48] While the Insider Defendants have been indicted, the FDA's testimony poses no threat to the Defendants' ability to assert the Fifth Amendment.

In *Clinton v. Jones,* the Supreme Court held that the district court abused its discretion by deferring trial until President Clinton left office, in part because "delaying trial would increase the danger of prejudice resulting from the loss of evidence, including the inability of witnesses to recall specific facts, or the possible death of a party."[49]

Here, the Tennessee Clinic Defendants cannot fully defend the cases against them and adequately prepare for trial without the FDA's testimony. Delaying the civil proceedings until after the criminal prosecution creates the unnecessary risk of undue and irreparable prejudice to the Tennessee Clinic Defendants through potential lost evidence and forgotten facts, evidence and facts central to the defense of these cases.

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The vast majority, if not all, of the seven *Microfinancial* factors weigh against staying the proceedings. The FDA failed to carry its burden of establishing the need for a stay of its deposition. Therefore, the Court should deny the FDA's Motion for Protective Order.

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[48] *Fed. Sav. & Loan Ins. Corp. v. Molinaro*, 889 F.2d 899, 903 (9th Cir. 1989) (quoting *Dresser*, 628 F.2d at 1376).
[49] 520 U.S. 681, 707-08 (1997).

CONCLUSION

The Court should grant the Tennessee Clinic Defendants' Motion to Compel[50] the FDA's 30(b)(6) deposition and deny the FDA's Motion for Protective Order.

Oral Argument Requested

The Tennessee Clinic Defendants request oral argument on this motion at the hearing before Chief Magistrate Judge Boal on May 28, 2015, at 11:30 EDT in Courtroom 14.

Respectfully submitted,

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[50] Dkt. 1775.

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of May, 2015, a true and accurate copy of the foregoing was filed via the Court's ECF system, to be served electronically upon those parties registered to receive ECF service.

/s/ Chris J. Tardio
Chris J. Tardio